



Prescription Policy Choices

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**Comments to the MaineCare Redesign Task Force  
12/11/12**

Commissioner Mayhew and other members of the MaineCare Redesign Task Force.

I'm Ann Woloson, Executive Director of Prescription Policy Choices, a nonprofit, nonpartisan public policy organization with the mission of improving access to effective, safe and affordable medicine in Maine and the US. We promote policy we believe helps to improve access to and reduce the cost of prescription drugs. PPC is primarily funded through foundation grants and policy contracts to promote greater use of evidence-based prescription drugs. We do not accept any funding from the pharmaceutical, medical device or insurance industries.

**I'm here today to thank you for your work and support your recommendations regarding improved monitoring of the use of antipsychotic medications with children and adults enrolled in MaineCare.** While it is important that children who can benefit from these drugs continue to have access, it's also important children who won't benefit and who are at risk of significant health consequences be protected from unnecessary or inappropriate prescribing. I suggest the recommendation include examples of models from other states, including Washington and Arkansas, both which experienced a 30% reduction in the use of these drugs with children in foster care after implementing a peer review and consultation program (see attached summary charts from Washington and Arkansas). These reductions were not about denying children access to needed medications, but rather about preventing their clinically inappropriate, non evidence-based use.

We have followed the State's work on this issue including attending Drug Utilization Review Board meetings where some initial steps have been taken to strengthen metabolic monitoring of children who are taking these drugs. While we appreciate these initial steps, we believe there is much more the state could do to reduce inappropriate or unnecessary use of these drugs with both children and adults in Maine, which could result in costs savings over a relatively short period of time.

For example, Maine participated in an AHRQ study of this issue which found that too many children were being prescribed too many of these drugs at too young an age. Another report put together by a workgroup in Maine found that children in state custody and foster care were being prescribed these drugs at higher rates than the national average. While the FDA has approved some of these drugs for use with children, that approval included strong cautions about overuse, and that such use be closely monitored for side effects and effectiveness and that the drugs only be used as long as needed.



The work group I mentioned actually created draft prescribing guidelines (attached) which I believe this committee was provided with early on in your deliberations. These guidelines include recommendations for base-line and ongoing monitoring and also recommend that certain children be tapered off the drugs after 6 months. These same recommendations are also included in the prescriber education module created by some of the same members of the work group previously mentioned. Again, those recommendations specify that the use of antipsychotic medication for children with aggression be used carefully and that children be tapered off the drugs after six months of treatment if the patient is doing well.

- **We suggest the task force consider recommending that DHHS promote the availability and use of these guidelines by prescribers in private practice and mental health clinics and also recommend a review of children who have been using these drugs for more than 6 months to see if such use is still necessary and/or beneficial.**

Given the side effects associated with these drugs, the high costs of the drugs and the lack of evidence regarding the effectiveness of long term use with children, the state has an opportunity to protect the health, safety and welfare of children with the added benefit of realizing savings that would likely occur as a result of such a review.

I also urge to committee to consider or reconsider other potential cost saving options related to prescription drug coverage that we believe could be achieved over both the short and long term, including:

- **Using some of the prescription drug settlement money that has recently come into the state to fill the short term needs to be addressed by the committee.**

I've attached a copy of press releases from the Attorney General's office regarding two recent prescription drug company settlements: One issued this past August related to the inappropriate marketing Risperdal, an atypical antipsychotic, which Maine received \$2.7 M. Another settlement announced last month related to alleged unlawful promotion of the diabetes drug, Avandia, where the manufacturer misrepresented its cardiovascular risks and safety profile, which Maine received or is about to receive \$1.5 M. I've also attached a page from the Risperdal settlement language which specifies what the funds can be used for including provider and consumer education, legal fees and other uses permitted by state law at the discretion of the Attorney General. Since Medicaid paid for these drugs, it seems appropriate that a portion of the settlement funds be returned to the program. I ask the Task Force to seek information about the status of these funds and request a portion be put back into the MaineCare program, and/or used for consumer and provider education to correct the misinformation provided by the drug companies in Maine.

- **Improve our generic utilization rate**



I've read the Nov. 17<sup>th</sup> memo from GHS and while I understand the State's pharmacy benefit manager has worked to increase utilization of quality, less expensive generics over time, a Lewin report released last year indicates Maine can do better. Even with large rebates, in most cases brands still cost more than generics. Generics are often associated with less risks and safety concerns – avoiding Vioxx and Avandia scenarios where significant adverse health consequences associated with these drugs were hidden by the manufacturer while heavily marketed to state programs using the lure of rebates, and then eventually pulled from the market due to safety concerns. In fact, Maine continued to list Avandia as preferred after information about health risks were released, even though there were evidence-based therapeutic alternatives available at a much lower cost. I've attached a list of the top 50 drugs purchased by MaineCare in 2011 indicating that the State is purchasing brand names drugs in many cases where therapeutic equivalents were available at a much lower cost. It's worth noting that many of the drugs at the top of the list are brand name antipsychotics.

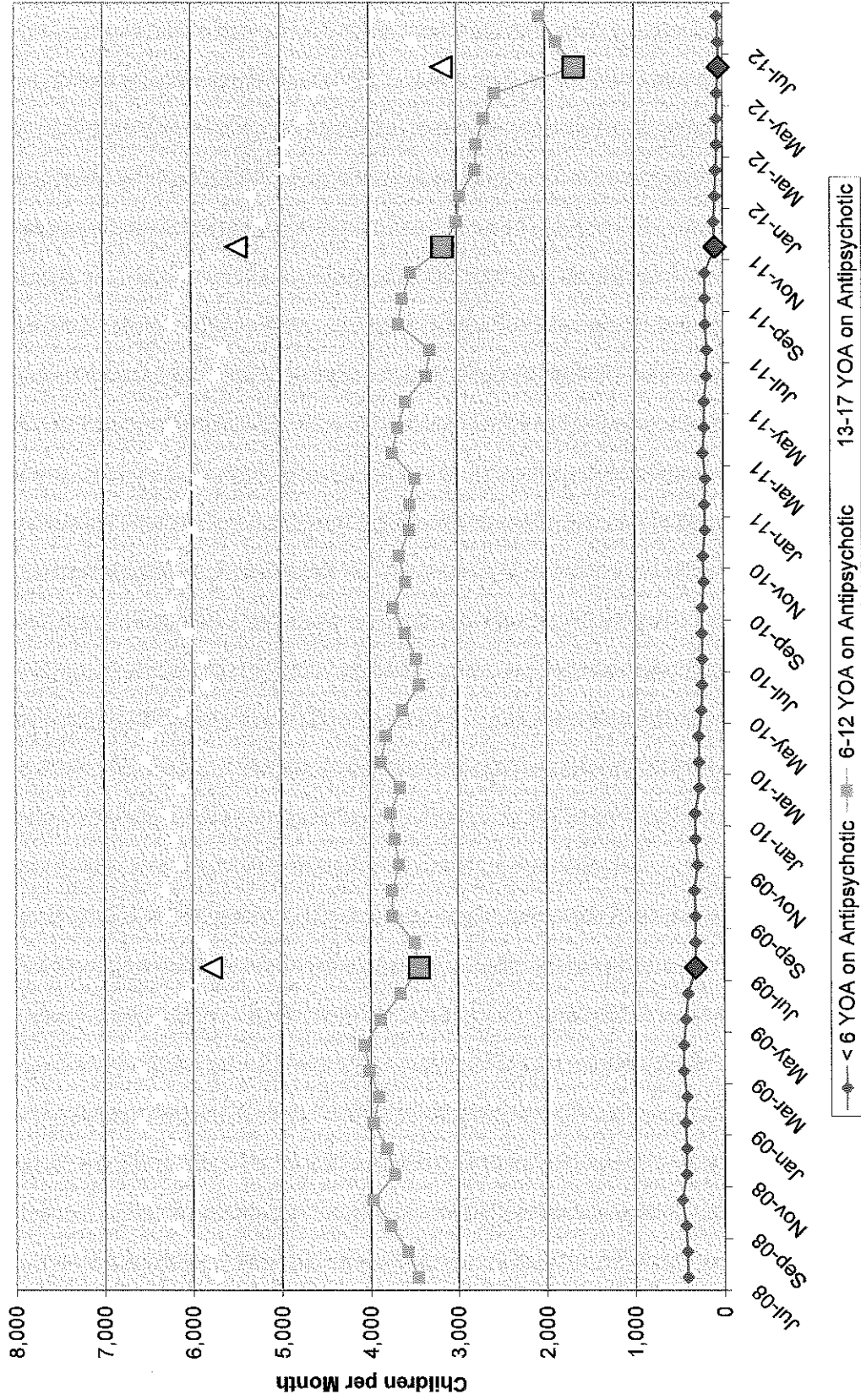
- **MaineCare should work to improve transparency regarding supplemental rebates negotiated by its pharmacy benefit manager for preferring a brand name drug over a less expensive therapeutic equivalent.** Without transparency on supplemental rebates, Maine cannot make informed decisions on Rx costs saving strategies related to the use of brand or generic drugs.

Again, while I believe the State's PBM has been successful in increasing the use of generic medications, it's difficult to know whether or not the MaineCare program is receiving the best value for the money it spends on prescription drugs without improved transparency regarding supplemental rebates.

Thanks for considering these comments.



Total Volume of Antipsychotics in AR Kids











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## Drugmaker to Pay Maine \$1.2 Million as Part of National Diabetes Drug Settlement

November 16, 2012

Attorney General's Office

AUGUSTA – Attorney General William J. Schneider has joined 37 other states in a \$90 million settlement with GlaxoSmithKline LLC (GSK), resolving allegations that the pharmaceutical company unlawfully promoted its diabetes drug, Avandia, by misrepresenting its cardiovascular risks and safety profile.

The settlement will bring more than \$1.2 million to the State of Maine.

"Patients rely on safety claims made by pharmaceutical companies," said Attorney General Schneider. "This settlement will help ensure that patients are not put at risk by misleading marketing."

A complaint and consent decree were filed in Kennebec County Superior Court on November 15, 2012 alleging that GSK promoted the diabetes drug to physicians and other healthcare providers with false and misleading representations about its safety and misrepresenting the drug's cardiovascular benefits. The drug may have actually increased patient risks.

Under the terms of the consent judgment, GSK has agreed to change how it markets and promotes diabetes drugs, and is prohibited from:

Making any false, misleading, or deceptive claims about any diabetes drug;

Making comparative safety claims that are not supported by substantial evidence or substantial clinical experience;

Presenting favorable information once thought valid but rendered invalid by contrary and more credible recent information;

Promoting investigational drugs; or

Misusing statistics or otherwise misrepresenting the nature, applicability, or significance of clinical trials.

The consent judgment also imposes, for at least eight years, a number of requirements relating to GSK's publication of its study results, including that it register and post all GSK-sponsored clinical trials as required by federal law.

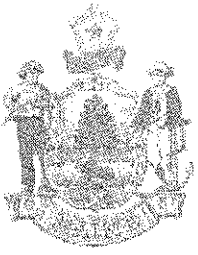
The investigation was led by the Attorneys General of Oregon and Illinois with an Executive Committee consisting of the Attorneys General of Arizona, Florida, Maryland, Pennsylvania, Tennessee, and Texas. Also participating in the settlement are Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Idaho, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Jersey, North Carolina, North Dakota, Ohio, Oklahoma, Rhode Island, South Dakota, Vermont, Washington, and Wisconsin.

This case was prosecuted by Assistant Attorney General Carolyn Silsby of Attorney General Schneider's Consumer Protection Division.



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# Maine Government News

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## Pharmaceutical Company Settles Claims of Misleading Marketing

August 30, 2012

Attorney General's Office

### Largest Multistate Consumer Protection Drug Settlement

AUGUSTA – Attorney General William J. Schneider announced today that Maine, along with 36 other State Attorneys General, reached a record \$181 million dollar settlement with Janssen Pharmaceuticals, Inc., a subsidiary of Johnson and Johnson.

A complaint and consent decree filed in Kennebec County Superior Court today resolved claims that Janssen violated the Maine Unfair Trade Practices Act when it improperly marketed the antipsychotic drugs Risperdal, Risperdal Consta, Risperdal M-Tab and Invega for unapproved or off-label uses. Risperdal is among a class of drugs known as atypical or second generation antipsychotics.

Maine will receive \$2.7 million as part of the settlement.

The complaint alleges that Janssen promoted Risperdal for off-label uses to both geriatric and pediatric patients, targeting those with Alzheimer's disease, dementia, depression and anxiety. Risperdal is approved to treat schizophrenia, bipolar disorder and behavior problems in teenagers and children with autism. While doctors may prescribe medicines as they see fit, companies are allowed to promote them for only uses approved by the U.S. Food and Drug Administration (FDA).

"The sales practices of pharmaceutical companies have increasingly come under scrutiny," said Attorney General Schneider. "As this lengthy investigation and resulting settlement shows, we are determined to curb illegal marketing that puts patients at risk."

According to the consent judgment, Janssen agreed to change not only how it promotes and markets its atypical antipsychotics but also agreed to refrain from any false, misleading or deceptive promotion of the drugs. Additionally, for a five-year period, Janssen:

Must clearly and conspicuously disclose, in promotional materials for atypical antipsychotic products, the specific risks identified in the black-box warning on its product labels;

Must present information about effectiveness and risk in a balanced manner in its promotional materials;

Shall not promote its atypical antipsychotics using selected symptoms of the FDA-approved diagnoses unless certain disclosures are made regarding the approved diagnoses;

Shall require its scientifically trained personnel, rather than its sales and marketing personnel, to develop the medical content of scientific communications to address requests for information from health care providers regarding Janssen's atypical antipsychotics;

Must refrain from providing samples of its atypical antipsychotics to health care providers whose clinical practices are inconsistent with the FDA-approved labeling of those atypical antipsychotics;

Must not use grants to promote its atypical antipsychotics nor condition medical education funding on Janssen's approval of speakers or program content;

Must contractually require medical education providers to disclose Janssen's financial support of their programs and any financial relationship with faculty and speakers;and

Must have policies in place to ensure that financial incentives are not given to marketing and sales personnel that encourage or reward off-label marketing.

This case was handled by Assistant Attorney General Christina Moylan of Attorney General Schneider's Consumer Protection Division.

The Attorneys General from Florida led the investigation into Janssen's marketing and promotional practices. The Attorneys General of the following states and the District of Columbia participated in the settlement: Alabama, Arizona, Colorado, Connecticut, Delaware, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maryland, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, Wisconsin and Wyoming.



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## Antipsychotic Medication Consent Worksheet

1. Full description of risks and benefits of medication is given to youth in age appropriate language
  - a. Youth 14 and over must consent unless there is an emergency (imminent danger of bodily harm to youth or others).
  - b. Consent must be given willingly and may not be obtained through coercion, as detailed in Rights of Recipients.
  - c. Youth under 14 should assent to use of medication.
2. Is this an urgent situation?
  - a. Definition of urgent
    - i. Youth likely to hurt self or others in next 60 days; or
    - ii. Youth likely to lose his/her living and/or school placement in next 60 days
  - b. If yes, consent can be given for 60 days even if the following steps have not been completed
  - c. If the situation is not urgent, the steps below must be followed in order for consent to be appropriate
  - d. Consent for urgent situations may not be given for consecutive 60 day periods without special permission by Program Administrator.
3. The Casework Review must be complete and shared with prescriber
  - a. Are psychosocial or environmental factors contributing to the youth's symptoms?
    - i. Recent placement change
    - ii. Family loss: e.g., distance, Termination of Parental Rights, separation from sibling(s), death
    - iii. Disruption of school setting or peer relationship
  - b. What actions/interventions are being done to promote stability and foster strong connections/emotional bonds with caretakers
4. The youth must have a complete psychiatric evaluation within the past year. If the youth has been hospitalized within the past year, the admission evaluation counts.
5. Is the target symptom psychosis or a manic episode?
  - a. If yes, consent is appropriate
    - i. Please list DSM-IV symptoms of psychosis or manic episode
    - ii. Skip to item 7
  - b. If no, continue to item 6
6. Is the target symptom aggression and/or severe emotion dysregulation?
  - a. For youth with Autism Spectrum Disorders:
    - i. A Functional Behavioral Assessment has been completed, and its recommendations been acted upon.
  - b. For aggression without autism:
    - i. The potential benefits of psychotherapy been maximized.
    - ii. The use of evidence based practices is preferred but is not a prerequisite for the use of antipsychotics. We are gathering data on



the access of foster youth on antipsychotics to EBP's; has an EBP been tried?

iii. Other medication responsive diagnoses have been treated. ADHD, Depression, and Anxiety are the most common.

7. Quantify, frequency, and severity (0-10) of most clinically relevant symptoms have been rated; this will be a baseline measure that will aid in evaluating response to medication.

8. Baseline measurements have been taken: weight, Body Mass Index (BMI); BMI percentile, pulse/blood pressure, Abnormal Involuntary Movements Scale (AIMS)

9. Baseline labs have been done: fasting lipids, fasting glucose.

10. Discuss diet and exercise recommendations with caregivers

11. **For continuation of antipsychotics**

a. Have risks and benefits of continuation been considered?


i. Are BMI and BMI percentile being tracked?

ii. Are pulse/blood pressure, fasting glucose, and fasting lipids being followed?

iii. Are frequency and severity of target symptoms being tracked?

b. If antipsychotic is being used for aggression:

i. Has youth's aggression substantially improved?

ii. If yes and antipsychotic has been used for 6 months, strongly consider an attempt to decrease the dose and move toward discontinuation. 



5. Use statistics on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case. If any results derived from pooling data are presented, Janssen shall disclose the method of pooling.

**VII. Terms Relating to Payment**

No later than 30 days after the Effective Date of this Judgment, Janssen shall pay \$181,047,437 to be divided and paid by Janssen directly to each Signatory Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. Said payment shall be used by the States as and for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, including future consumer protection enforcement, consumer education, litigation, or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, and may be used to fund or assist in funding programs directed at mental illness treatment, including but not limited to education and outreach or for other uses permitted by state law, at the sole discretion of each Signatory Attorney General. The Parties acknowledge that the payment described herein is not a fine, penalty, or payment in lieu thereof.

STATE OF MAINE  
KENNEBEC, SS.

SUPERIOR COURT  
CIVIL ACTION  
Docket No.

STATE OF MAINE	)
	)
Plaintiff	)
	)
v.	)
	)
JANSSEN PHARMACEUTICALS, INC. and	)
JOHNSON & JOHNSON	)
	)
Defendants	)

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**FINAL JUDGMENT AND CONSENT DECREE**

The Plaintiff, State of Maine, by its Attorney General, William J. Schneider, having filed an action pursuant to the Maine Unfair Trade Practices Act, 5 M.R.S. § 205-A *et seq.*, and the parties having consented to entry of this Final Judgment and Consent Decree ("Judgment").

**NOW THEREFORE**, upon the Judgment of the parties hereto, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:**

**PARTIES**

1. The State of Maine, by and through its Attorney General, is the plaintiff in this case. The Attorney General commenced this action pursuant to his responsibility for enforcing the Maine Unfair Trade Practices Act.

2. Janssen Pharmaceuticals, Inc. ("Janssen") is a subsidiary of Johnson & Johnson. Janssen does business in the state of Maine. Janssen's executive offices are located at 1125 Trenton Harbourton Road, P.O. Box 200, Titusville, NJ 08560. Johnson & Johnson's executive offices are located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. At all times relevant hereto, Janssen engaged in trade affecting consumers, within the meaning of the Maine

MaineCare Prescription Drugs List; Data Request # 41460  
 Data limited to Paid & Reversed Rx claims in calendar year 2011  
 Data Source MHIMS DSS  
 Run Date 13-Mar-2012

Atyp B  
 ADHD Brand  
 Atyp Brand  
 ADHD B  
 Atyp Brand

Product Name	Claims Paid	Charge Submitted	Net Pay	Avg paid per claim
SUBOXONE	63,205	\$15,245,840.70	\$11,716,173.90	\$185.37
ABILIFY	38,583	\$14,351,602.90	\$9,182,952.99	\$238.01
SEROQUEL	42,812	\$14,061,655.88	\$9,109,463.33	\$212.78
ADDERALL XR	42,962	\$10,097,332.54	\$7,950,290.22	\$185.05
CONCERTA	41,009	\$8,322,645.74	\$6,606,302.98	\$161.09
ADVAIR DISKUS	59,304	\$10,569,905.78	\$6,143,953.70	\$103.60
SINGULAIR	51,127	\$8,388,678.12	\$5,130,204.75	\$100.34
ZYPREXA	17,292	\$8,588,533.99	\$5,035,735.26	\$291.22
CYMBALTA	55,063	\$7,958,527.36	\$4,933,766.84	\$89.60
LIPITOR	69,945	\$7,809,938.39	\$3,954,499.94	\$56.54
VYVANSE	29,306	\$4,636,297.31	\$3,533,233.88	\$120.56
ATRIPLA	1,834	\$3,574,239.76	\$2,725,648.17	\$1,486.18
GEODON	12,413	\$4,256,885.44	\$2,597,431.66	\$209.25
LEXAPRO	47,424	\$4,084,428.39	\$2,495,963.49	\$52.63
FOCALIN XR	15,883	\$2,933,372.94	\$2,230,661.45	\$140.44
FLOVENT HFA	23,916	\$3,243,602.30	\$2,154,039.77	\$90.07
SPIRIVA HANDIHALER	33,179	\$4,669,612.03	\$2,117,645.43	\$63.82
VALTREX	10,477	\$2,504,026.93	\$2,071,113.60	\$197.68
PROAIR HFA	70,112	\$2,747,914.95	\$1,888,428.68	\$26.93
NOVOLOG	12,066	\$2,670,920.31	\$1,856,423.50	\$153.86
DEXILANT	18,380	\$3,405,312.55	\$1,728,208.92	\$94.08
COPAXONE	608	\$2,307,235.34	\$1,714,409.89	\$2,819.75
VENLAFAXINE HCL ER	36,532	\$4,223,891.84	\$1,571,441.35	\$43.02
COMBIVENT	23,005	\$2,878,073.92	\$1,544,351.03	\$67.13
ACTOS	13,563	\$2,738,355.92	\$1,502,084.79	\$110.75
TRUVADA	1,783	\$2,156,591.64	\$1,492,921.20	\$837.31
STRATTERA	10,849	\$2,075,179.07	\$1,472,647.00	\$135.74
LANTUS	22,627	\$2,675,196.90	\$1,453,308.53	\$64.23
PROTONIX	10,328	\$1,905,621.66	\$1,451,707.92	\$140.56
OXYCONTIN	11,794	\$3,024,634.49	\$1,378,999.99	\$116.92
ONETOUCH ULTRA BLUE	9,322	\$1,712,819.10	\$1,356,452.89	\$145.51
LEVEMIR	8,892	\$1,923,348.90	\$1,344,498.31	\$151.20
VENTOLIN HFA	54,963	\$2,067,742.68	\$1,338,795.54	\$24.36
HUMIRA PEN	886	\$1,692,608.23	\$1,277,071.44	\$1,441.39
MARINOL	1,070	\$1,482,637.25	\$1,273,245.00	\$1,189.95
LYRICA	16,689	\$2,208,456.36	\$1,261,705.54	\$75.60
PEGASYS	591	\$1,473,111.42	\$1,219,594.81	\$2,063.61
INCIVEK	99	\$1,564,894.65	\$1,210,117.97	\$12,223.41
PLAVIX	25,075	\$2,890,308.48	\$1,207,785.77	\$48.17
NASONEX	16,902	\$1,791,466.47	\$1,206,673.87	\$71.39
LOVENOX	1,635	\$1,532,293.66	\$1,185,246.96	\$724.92
OXYCODONE HCL	93,046	\$5,277,711.93	\$1,133,033.94	\$12.18
SYNAGIS	641	\$1,441,833.72	\$1,083,323.18	\$1,690.05
ENBREL	834	\$1,427,571.34	\$1,079,551.38	\$1,294.43
GENOTROPIN	371	\$1,340,284.54	\$1,044,829.32	\$2,816.25
BENEFIX	113	\$1,909,311.28	\$1,043,986.49	\$9,238.52
FREESTYLE LITE TEST STRIP	7,733	\$1,268,229.31	\$1,007,737.87	\$130.32
TRICOR	14,108	\$1,535,921.25	\$957,354.65	\$67.86
HUMIRA	580	\$1,176,653.47	\$891,593.57	\$1,537.23
PULMOZYME	510	\$1,353,885.71	\$884,735.60	\$1,734.78

